ORIGINAL ARTICLE

Indonesian Journal of Blood and Transfusion (*IDJBT*) 2024, Volume 2, Number 1 : 16-20
P-ISSN 3032-7520

Published by
The Indonesian Society Blood Transfusion Physician

Critical Control Point Production Blood Components of Platelets

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ABSTRACT

Introduction: Blood transfusion is a health service effort in the form of medical actions giving directions to patients for the purpose of healing diseases and restoring health. The transfused concentrated platelet component must be able to provide the maximum therapeutic effect with the least possible reaction. This means that each bag of concentrated platelets produced must contain a sufficient number of platelets so that it is effective for patient safety. This study aims to describe how to obtain concentrated platelet products that have platelet levels in accordance with established standards by meeting critical control points for making concentrated platelet components.

Methods: This study uses a type of descriptive research with a quantitative approach which was carried out at the Indonesian Red Cross Blood Donor Unit of Tangerang City. The samples in this study were concentrated platelet products from Blood Transfusion Unit A as many as 16 samples. The sampling technique used is random sampling data processed using Microsoft Excel.

Result: Based on the results of the platelet product quality test inspection with a Refrigerated Centrifuge, the first round trial of the first round of 2000 XG for 3 minutes at temperature 22°C with RC acceleration 9 and RC deceleration 4. Based on the results of the product quality test examination in February, it can be concluded that the TC blood component as many as 4 bags, the results of hematological examination on platelet levels show 0% results.

Conclusion: It can be concluded that the TC blood component as many as 4 bags, the results of hematology examination on platelet levels show 0% results. Critical Control Point is obtained, blood collection with one puncture, no repositioning, duration of collection less than 12 minutes, transportation of raw materials at 20-24°C, processing duration less than 8 hours, product storage at 20-24°C by agitation and closed.

Keywords: Platelets, Critical Control Point, Product Quality Test Testing.
Cite This Article: Asiah, N., Azam, N., Rifai, T.B., Sidabutar, D.H., Jumansyah, O. 2024. Critical Control Point Production Blood Components of Platelets. *Indonesian Journal of Blood and Transfusion* 2(1): 16-20

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Received: 2024-02-04
Accepted: 2024-03-19
Published: 2024-04-16

INTRODUCTION

Blood transfusion is the process of giving blood/blood components from healthy people (donors) to sick people (recipients/sufferers). Blood transfusions are important clinical measures in improving the health of patients who need blood, treating diseases, and saving lives. The right indication for transfusion of blood and blood components is the treatment of significant morbidity and mortality that cannot be treated by other means.[1]

Blood transfusion is a health service effort in the form of medical actions given directions to patients for the purpose of curing diseases and restoring health.[2] Platelet transfusions are given to patients with thrombocytopenia conditions, patients with platelet function abnormalities, and patients who experience bleeding, with the aim of preventing and stopping bleeding.[3]

Transfusion of blood components is given according to indications, platelet transfusion is only given to patients with spontaneous and massive bleeding with platelet counts of <100,000/µL.[4] The purpose of blood transfusion is to restore normal blood volume, replace the lack of blood components, and increase oxygenation and hemostasis. The basic indication of the use of blood components is not only efficient, economical, but also to minimize transfusion reactions.[5]

The transfused concentrated platelet component must be able to provide the maximum therapeutic effect with the least possible reaction. In this case, it means that each bag of concentrated platelets produced must contain a sufficient number of platelets so that it is effective for patient safety.[6–9] To produce quality platelet components with a single platelet number per final unit of >60 x 10^9, it must ensure inputs, processes, and outputs are carried out in accordance with the regulation of the Minister of Health of the Republic of Indonesia Number 91 of 2015.[4] Based on the above background, the researcher wants to conduct a study entitled Critical Control Point for Making Platelet Blood Components.

This study aims to describe how to obtain concentrated platelet products that have platelet levels in accordance with established standards by meeting critical control points for making concentrated platelet components.

METHODS

Study Design

This research uses a type of descriptive research with a quantitative approach which was carried out at Indonesian Red Cross Blood Donor Unit of Tangerang City in February -May 2023. Descriptive research is research that seeks to describe a symptom, event, or event that occurs at the present moment.[10] Meanwhile, quantitative research is a research method based on concrete data in the form of numbers to produce a conclusion.[10]

Data Collection

The sample in this study was a concentrated platelet product from Blood Transfusion Unit A. The sampling technique used was random sampling which is a random sample selection technique without providing equal opportunities for all members of the population. The number of samples in this study was 16 samples.

Variable of the Study

The variables collected in this research are the results of quality test examination, platelet hematology examination, and bacterial contamination inspection.

Data Analysis

The research data that has been collected is then processed and analyzed using the Microsoft Excel 2020 program.

RESULTS

Product Quality Test Inspection February 2023

The quality test examination was carried out in February 2023 on TC blood components as many as 4 bags of TR 350 ml bag type, using the first round of 2000 XG experiments for 3 minutes with temperature 22°C with RC acceleration 9 and RC deceleration 4. The results of platelet hematology examination of the first bag 29.48 X 10^9, the second bag 10.03 X 10^9, the third bag 45.18 X 10^9, the fourth bag 37.44 X 10^9. Based on the 75% acceptance criteria standard, the test results obtained were 0%, the four bags were declared Not Pass platelet values <47 X 10^9.

Product Quality Test Inspection March 2023

The quality test examination was carried out in March 2023 on TC blood components as many as 4 bags of TR 350 ml bag type, using the second round of 2000 XG experiment for 3 minutes with temperature 22°C with RC acceleration 7 and RC deceleration 4. The results of the platelet examination of the first bag are 12.60 X 10^9, the second bag is 36.88 X 10^9, the third bag is 38.14 X 10^9, and the fourth bag is 43.94 X 10^9. Based on the 75% acceptance criteria standard, the test results obtained were 0%, and the four bags were declared Not Pass platelet values <47 X 10^9.

The quality test examination was carried out in April 2023 on TC blood components as many as 4 bags of TR 350 ml bag type, using the third round of 2000 XG experiment for 3 minutes with temperature 22°C with RC acceleration 8 and deceleration 4. The platelet examination results of the first bag 94 X 10^9, the second bag 65 X 10^9, the third bag 71 X 10^9, the fourth bag 61 X 10^9. Based on the 75% acceptance criteria standard, the test results obtained were 100%, the four bags were declared to have passed the platelet value of >47 X 10^9.

Product Quality Test Inspection May 2023

The quality test examination will be carried out in May 2023 on TC blood components as many as 4 bags of TR 350 ml bags, using the third round of 2000 XG for 3 minutes with temperature 22°C with RC acceleration 8 and deceleration 4. The platelet examination results of the first bag are 56 X 10^9, the second bag is 55 X 10^9, the third bag is 74 X 10^9, the fourth bag is 62 X 10^9. Based on the 75% acceptance criteria standard, the test results obtained were 100%, the four bags were declared to have passed the platelet value of >47 X 10^9.

DISCUSSION

Blood transfusions are important clinical measures in improving the health of patients who need blood, treating diseases, and saving lives. The right indication for transfusion of blood and blood components is the treatment of significant morbidity and mortality that cannot be treated by other means.[1] Transfusion becomes more effective with the processing of components from one complete blood bag. Blood components provide treatment options to clinicians in treating patients who respond better to blood components than to whole blood or if needed to minimize transfusion volume. Transfusion of concentrated platelet components is given to bleeding patients with thrombocytopenia due to massive transfusion, dengue hemorrhagic fever or dengue hemorrhagic fever, thrombocytopathy (platelet function damage), leukemia or aplastic anemia with bleeding.[8,11,12]

Platelets are pieces of blood circulating in the blood that are involved in the mechanism of cell-level hemostasis that gives rise to blood clotting (thrombus). Platelets have mucopolysaccharide walls that function in platelet adhesion and aggregation reactions. The function of platelets is to repair blood vessel damage and initiate a chain reaction for blood clotting.[11,13–15] Thrombocyte concentrate is the part of whole blood that contains platelet concentrate separated by centrifugation. Thrombocyte concentrate comes from one unit of complete blood (350-450 mL) and the processing process is carried out less than 6 hours after the blood is tapped. Concentrated platelets from both complete blood and apheresis should be stored under conditions that ensure optimal survival and hemostatic activity are maintained. Storage temperature should be between 20-24°C. Platelets agitate slowly and continuously during storage to ensure the availability of oxygen in platelets (agitation should be as slow as possible). Storage times should be determined in accordance with government regulations.[14,15]

Based on the results of the platelet product quality test inspection with evaluation Refrigerated Centrifuge rotation program (XG) from February until May, from the results of research that has been carried out. Based on the 75% acceptance criteria standard, the results of the product quality test examination in February and May, it can be concluded that the TC blood component as many as 4 bags, the results of the hematological examination on platelet levels show 0%

	Physical Examination						pH > 6.4	Haematology Examination		Bacterial Contamination Inspection	
	Bag Number	Blood Type	Blood Tapping Procedure	Exp Date	Volume > 31 mL (350) > 40 ml (450)	Swirl		Platelets >47 X 10^9 (350) >60 X 10^9 (450)	Leukocyte <0.15 X 10^9	Aerobes Negative	Anaerobic Negative
1	C3381745B	A Post	30-01-23	4-02-23	78	Exist	7,0	29.48 X 10^9	0.00 X 10^9	Negative	Negative
2	C2381775B	B Post	30-01-23	4-02-23	79	Exist	7,4	10.03 X 10^9	0.00 X 10^9	Negative	Negative
3	C3383472B	O Post	30-01-23	4-02-23	82	Exist	7,4	45.18 X 10^9	0.03 X 10^9	Negative	Negative
4	C2381726B	AB Post	30-01-23	4-02-23	80	Exist	7,4	37.44 X 10^9	0.01 X 10^9	Negative	Negative
Passing Standard %					75%	100%	75%	75%	75%	100%	100%
Examination Results %					100%	100%	100%	0%	100%	100%	100%

	Physical Examination						pH > 6.4	Haematology Examination		Bacterial Contamination Inspection	
	Bag Number	Blood Type	Blood Tapping Procedure	Exp Date	Volume > 31 mL (350) > 40 ml (450)	Swirl		Platelets >47 X 10^9 (350) >60 X 10^9 (450)	Leukocyte <0.15 X 10^9	Aerobes Negative	Anaerobic Negative
1	Y2101417B	O Post	14-03-23	19-03-23	57	Exist	7,0	12.60 X 10^9	0.00 X 10^9	Negative	Negative
2	Y3092718B	AB Post	13-03-23	18-03-23	58	Exist	7,4	36.88 X 10^9	0.01 X 10^9	Negative	Negative
3	Y1092441B	O Post	14-03-23	19-03-23	51	Exist	7,4	38.14 X 10^9	0.00 X 10^9	Negative	Negative
4	C1383347B	AB Post	13-03-23	18-03-23	55	Exist	7,4	43.94 X 10^9	0.00 X 10^9	Negative	Negative
Passing Standard %					75%	100%	75%	75%	75%	100%	100%
Examination Results %					100%	100%	100%	0%	100%	100%	100%

	Physical Examination						pH > 6.4	Haematology Examination		Bacterial Contamination Inspection	
	Bag Number	Blood Type	Blood Tapping Procedure	Exp Date	Volume > 31 mL (350) > 40 ml (450)	Swirl		Platelets >47 X 10^9 (350) >60 X 10^9 (450)	Leukocyte <0.15 X 10^9	Aerobes Negative	Anaerobic Negative
1	R9602003B	O Post	26-04-23	01-05-23	55	Exist	6,7	94 X 10^9	0.01 X 10^9	Negative	Negative
2	R9605206B	A Post	26-04-23	01-05-23	53	Exist	7,1	65 X 10^9	0.01 X 10^9	Negative	Negative
3	R9605740B	A Post	26-04-23	01-05-23	54	Exist	6,8	71 X 10^9	0.03 X 10^9	Negative	Negative
4	R9608553B	O Post	26-04-23	01-05-23	53	Exist	7,0	61 X 10^9	0.02 X 10^9	Negative	Negative
Passing Standard %					75%	100%	75%	75%	75%	100%	100%
Examination Results %					100%	100%	100%	100%	100%	100%	100%

	Bag Number	Blood Type	Physical Examination		Volume > 31 mL (350) > 40 ml (450)	Swirl	pH > 6.4	Haematology Examination		Bacterial Contamination Inspection	
			Aftap Date	Exp Date				Platelets >47 X 10^9 (350) >60 X 10^9 (450)	Leukocyte <0.15 X 10^9	Aerobes Negative	Anaerobic Negative
1	R9603527B	A Post	22-05-23	27-05-23	53	Exist	7,1	56 X 10^9	0.03 X 10^9	Negative	Negative
2	R9602795B	AB Post	22-05-23	27-05-23	54	Exist	7,3	55 X 10^9	0.01 X 10^9	Negative	Negative
3	R9601207B	O Post	23-05-23	27-05-23	59	Exist	7,3	74 X 10^9	0.01 X 10^9	Negative	Negative
4	R9602055B	B Post	23-05-23	28-05-23	58	Exist	7,3	62 X 10^9	0.01 X 10^9	Negative	Negative
Passing Standard %					75%	100%	75%	75%	75%	100%	100%
Examination Results %					100%	100%	100%	100%	100%	100%	100%

results. We got an increased platelet value in April and May, the test results obtained were 100%, and the four bags were declared to have passed the platelet value of >47 x 10^9. The result of the platelet standard from 0% to 100% occurs after changed rotation program Refrigerated Centrifuge includes time, temperature, acceleration, and deceleration, this becomes a critical control point for the processing of platelet blood components process by Regulation of the Minister of Health of the Republic of Indonesia number 91 year 2015 about standards concerning blood transfusion service standards.[4]

For this reason, it is important to carry out internal quality testing of platelet blood products in each blood transfusion unit and evaluate and analyze the rotation program Refrigerated Centrifuge including time, temperature, acceleration, deceleration and monitoring the input-to-output process for making platelets in accordance with product manufacturing standards good and correct platelets.[4]

CONCLUSION

Re-analysis is carried out by looking at the rotation speed and playback time specifically that first round experiment of the first round of 2000 XG for 3 minutes with temperature with RC acceleration 9 and RC deceleration 4. Based on the results of the product quality test examination in February, it can be concluded that the TC blood component is as many as 4 bags, and the results of the hematological examination on platelet levels show 0% results. Second round experiment 2000 XG for 3 minutes with temperature with RC acceleration 7 and RC deceleration 4. Based on the results of the product quality test examination in March, it can be concluded that the TC blood component has as many as 4 bags, and the results of the hematology examination on platelet levels show 0% results. Third round experiment 2000 XG for 3 minutes with temperature with the acceleration of RC 8 and the deceleration of RC 4 product quality tests in April and May, it can be concluded that TC blood components as many as 4 bags of hematological examination results on platelet levels show 100% results. Obtained Critical Control Point, blood collection with one puncture, no repositioning duration of collection less than 12 minutes, transportation of raw materials at 20-24ºC, processing duration less than 8 hours, product storage at 20-24ºC by agitation and closed. Monitor the processing of platelet blood components in accordance with the Critical Control Point of platelet manufacturing starting from input and process in accordance with the Regulation of the Minister of Health of the Republic of Indonesia number 91 year 2015 standards concerning Blood Transfusion Service Standards.

DISCLOSURES

Ethical Considerations

Ethical approval was obtained from The Health Research Ethics Committee (No.131/EC-KEP-UD/VI/2023).

Conflict of Interest

The authors have no conflict of interest.

Author Contribution

All authors similarly contribute to the think about from the investigate concepts, information acquisitions, information investigation, factual investigations, changing the paper, until detailing the consider comes about through publication.

Funding

The authors are responsible for all the study funding by completely using personal funding without a grant or any external funding sources.

REFERENCES

1. Harsiwi UB, Arini LDD. Tinjauan Kegiatan Donor Darah Terhadap Kesehatan Di Pmi Karanganyar, Jawa Tengah Tahun 2018. J Ilm Rekam Medis dan Inform Kesehat. 2018;8(1):50–6.
2. Ministry of Health Republic of Indonesia. Decree of the Minister of Health of the Republic of Indonesia Number HK.01.07/MENKES/9845/2020 about National Guidelines for Medical Services for the Management of Dengue Infection in Adults. Minister of Health of the Republic of Indonesia, Jakarta. Jakarta; 2022.
3. Astuti D. Nilai Indeks Trombosit Sebagai Kontrol Kualitas Komponen Konsentrat Trombosit. Meditory J Med Lab. 2021;8(2):85–94.
4. Ministry of Health of the Republic of Indonesia. Regulation of the Minister of Health of the Republic of Indonesia Number 91 of 2015 concerning Quality Standards for Blood Transfusion Services. Jakarta; 2015.
5. Nency YM, Sumanti D. Latar Belakang Penyakit pada Penggunaan Transfusi Komponen Darah pada Anak. Sari Pediatr. 2016;13(3):159.
6. Jay S Raval, Joseph R Griggs, Antonny Flegg. Blood Product Transfusion in Adults- Indications, Adverse Reactions, and Modifications. Am Fam Physician. 2020;102(1):30–8. Available from: https://www.aafp.org/pubs/afp/issues/2020/0701/p30.html

7. van der Meer PF, Dumont LJ, Lozano M, Bondar N, Wong J, Ismay S, et al. Aggregates in platelet concentrates. Vox Sang. 2015;108(1):96–100.
8. Basu D, Kulkarni R. Overview of blood components and their preparation. Indian J Anaesth. 2014;58(5):529–37.
9. Yusmaidi, Oktobiannobel J, Nur M, Bella Sabila Dananda. Derajat Toksisitas Hemoglobin Pada Penderita Kanker Kolorektal Yang Mendapat Kemoterapi CapeOX. Arter J Ilmu Kesehat. 2020;1(4):299–305.
10. Soendari T. Metode penelitian deskriptif. Bandung, UPI. Bandung: UPI; 2012.
11. Solves Alcaina P. Platelet Transfusion: And Update on Challenges and Outcomes. J Blood Med. 2020;11:19–26.
12. Capraru A, Jalowiec KA, Medri C, Daskalakis M, Zeerleder SS, Mansouri Taleghani B. Platelet Transfusion-Insights from Current Practice to Future Development. J Clin Med. 2021;10(9).
13. Stolla M, Refaai MA, Heal JM, Spinelli SL, Garraud O, Phipps RP, et al. Platelet transfusion - the new immunology of an old therapy. Front Immunol. 2015;6:28.
14. Cognasse F, Hamzeh-Cognasse H. Platelet-derived immune-modulatory mediators and transfusion: time to consider their effects? Blood Transfus. 2022;20(3):177–9.
15. Wandt H, Schäfer-Eckart K, Greinacher A. Platelet transfusion in hematology, oncology and surgery. Dtsch Arztebl Int. 2014;111(48):809–15.